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(54) Pump with disposable cassette for feeding fluid to a patient

(57) The cassette comprises a body 12 with an inlet 14 and an outlet 16 and a bellows member 72 defining a pump chamber is attached to the body by snap-on ribs 24, 66 securing a seal between spigot 68 and inner wall 70. Inlet and outlet valves are formed by resilient members 36 which are sealed into the body by cover plate 46. Operating rods with heads 52 and ball-ends 60 are movable axially to stretch the members 36 and thereby disengage lips 38 from respective valve seats 30.

The pump drive mechanism comprises a rocker 106 acting on the heads 52 through plungers 108 and 110 to operate the inlet and outlet valves alternately. It also has a drive member engageable with coupling 74 and linearly reciprocable to expand and contract the bellows. Synchronous operation is effected by a rotary stopper motor through cam mechanisms.

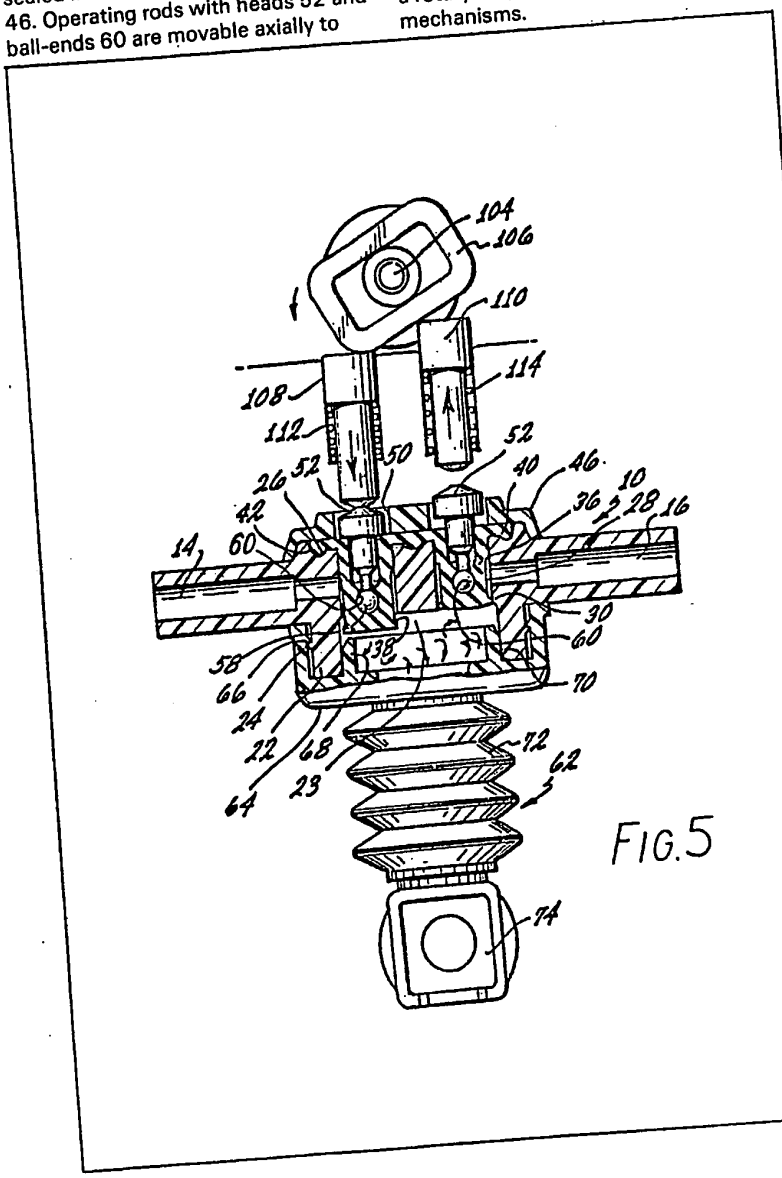

FIG.5

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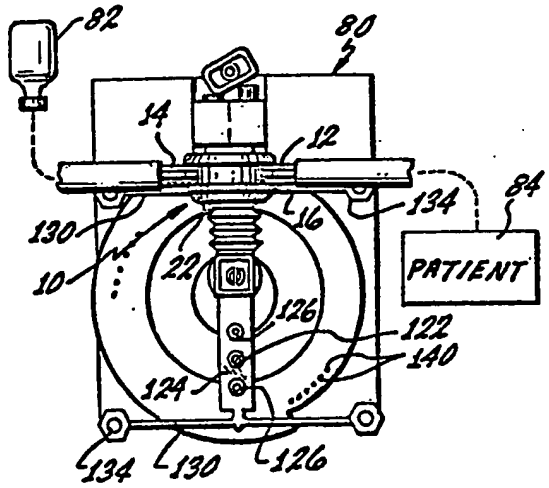
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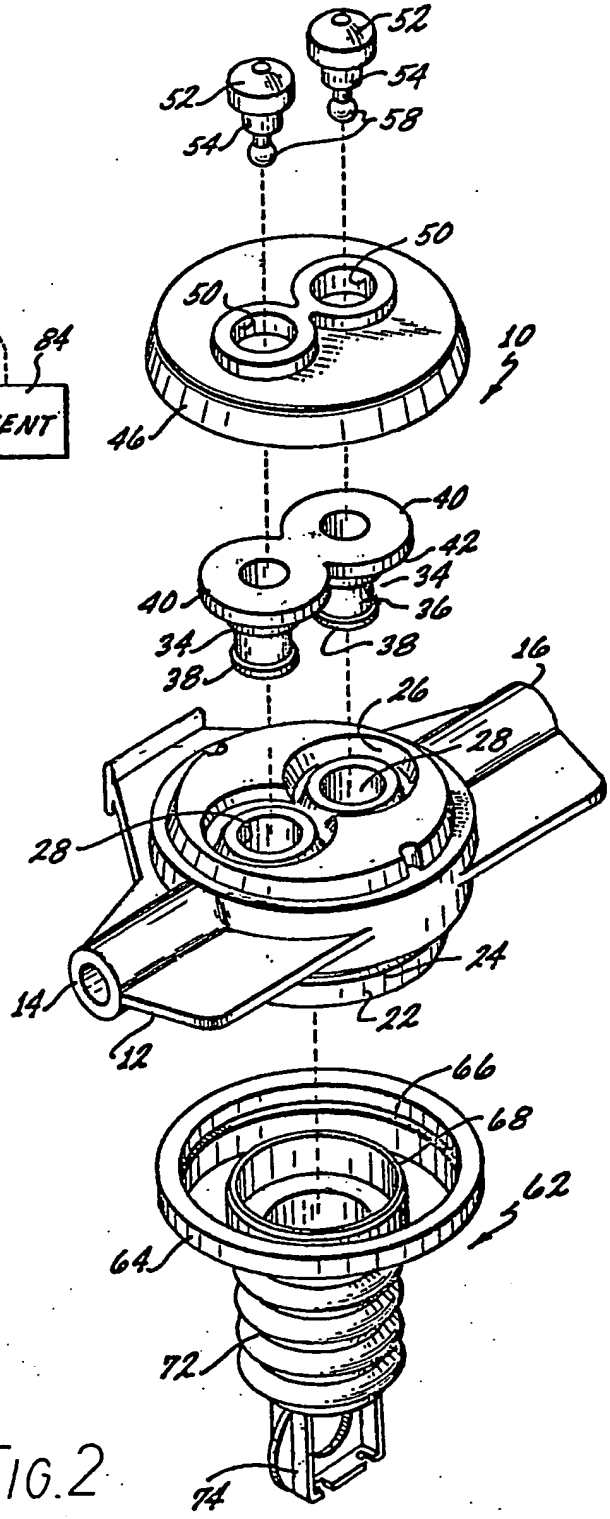
126

FIG.1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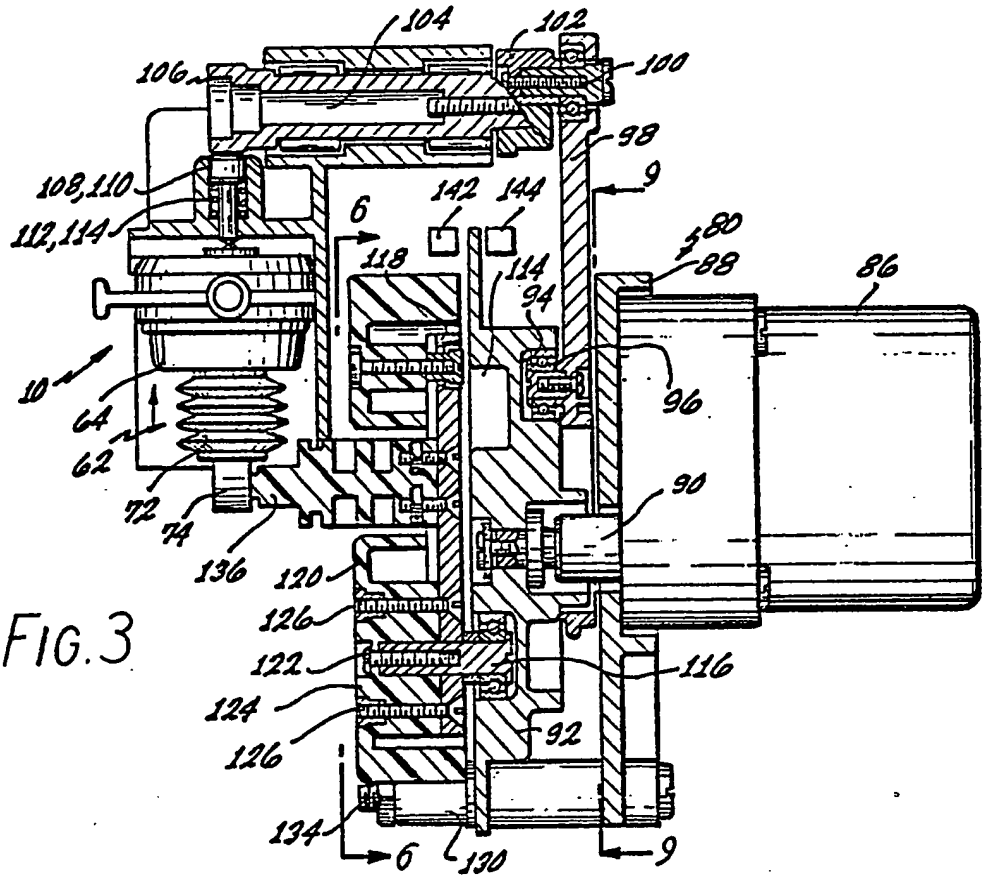
74

FIG.2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9
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112,114
6
80
88
86
118
114
94
10
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126
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116
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92
134
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130
9

FIG. 3

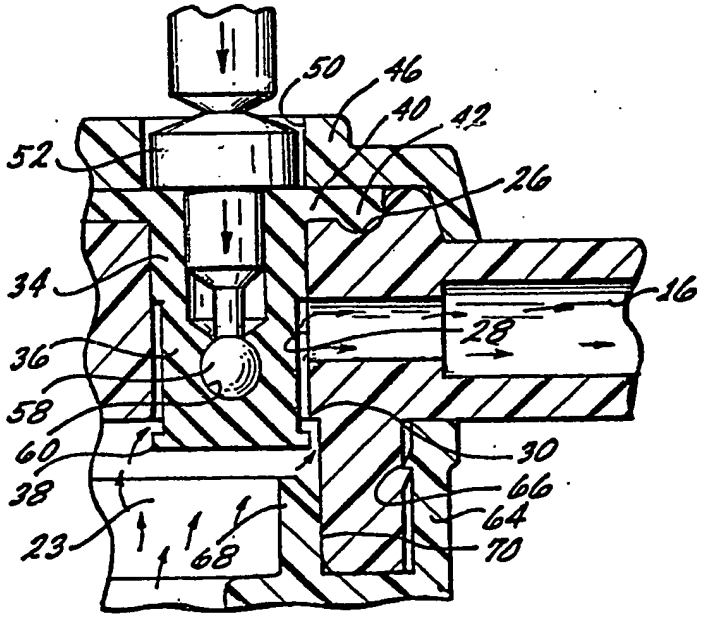
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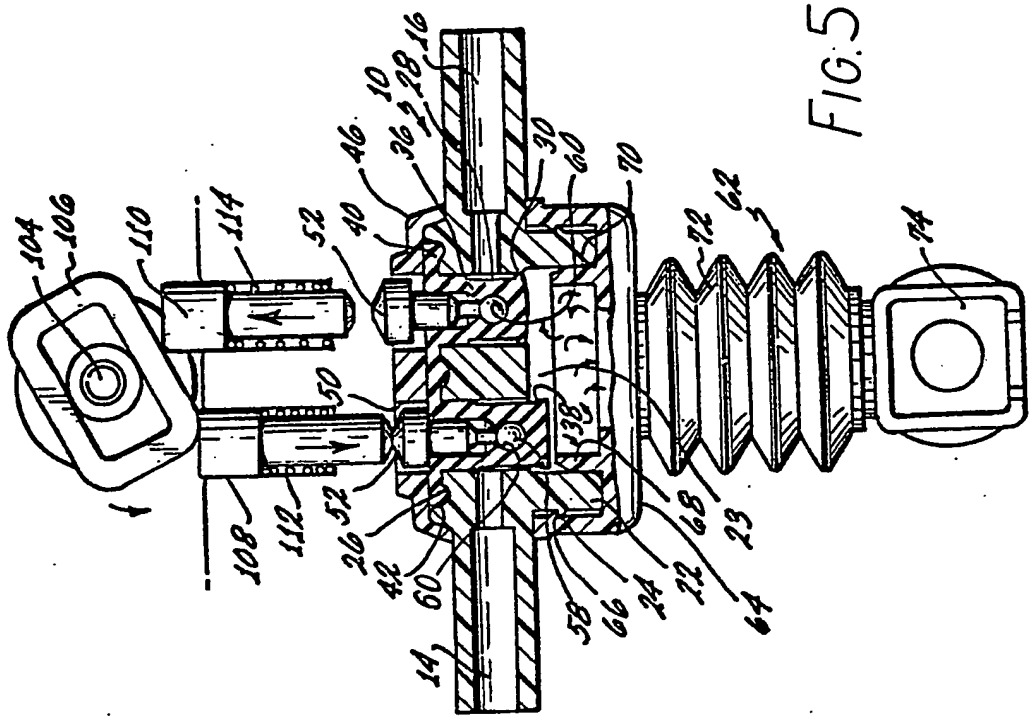
FIG. 10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74
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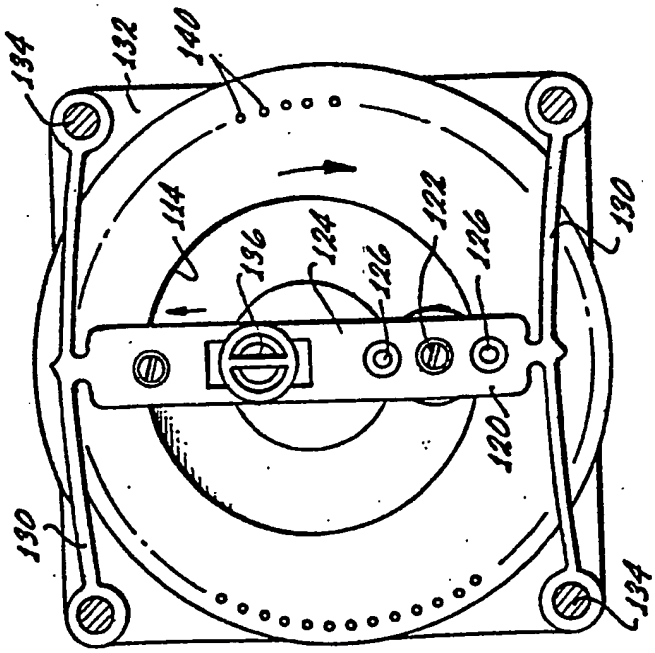
FIG.5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120
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134

FIG.4

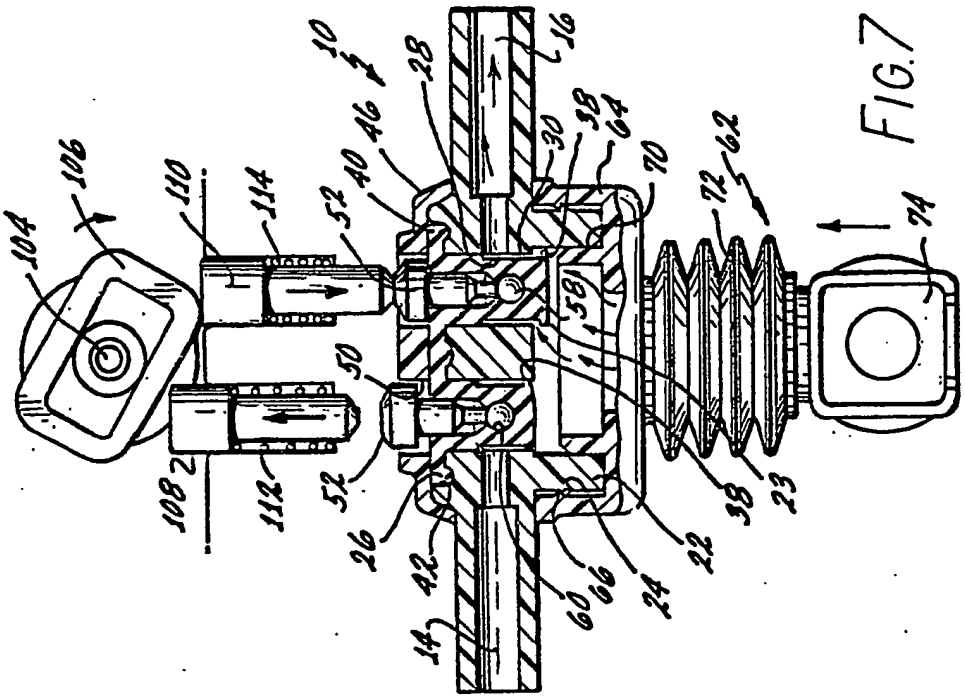
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FIG.7

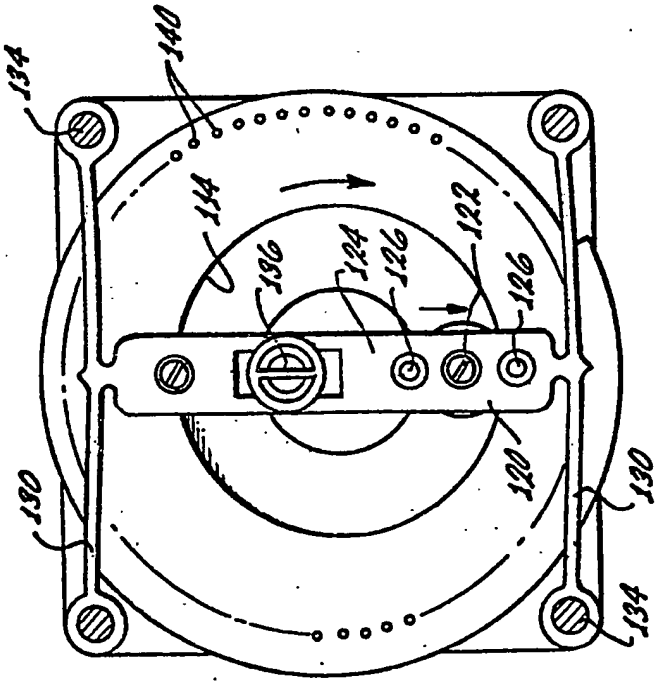
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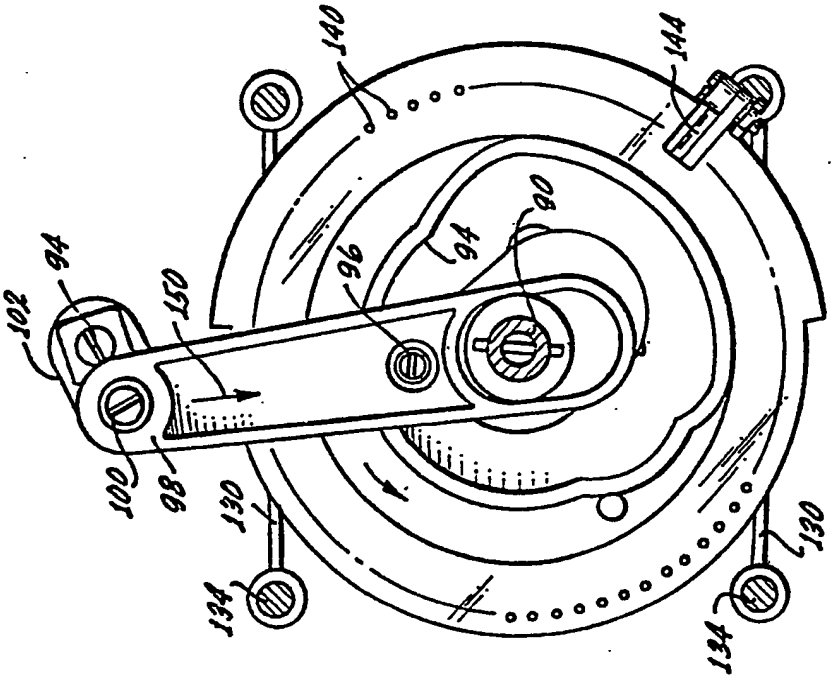
FIG.6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96
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98
130
134

FIG.9

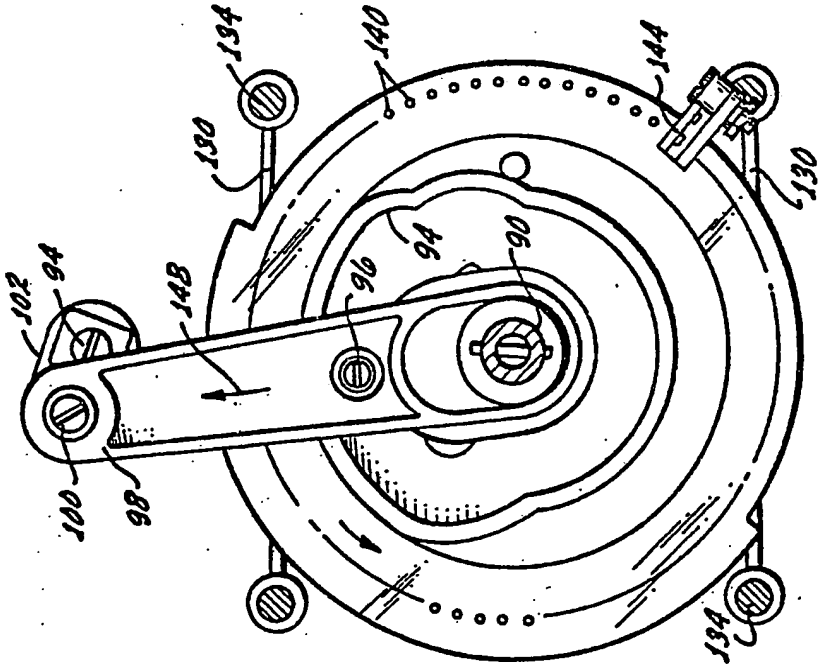
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FIG.8

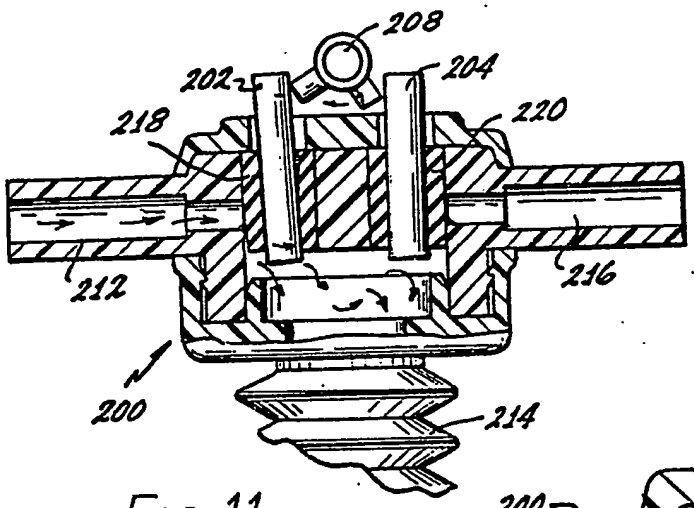

FIG. 11

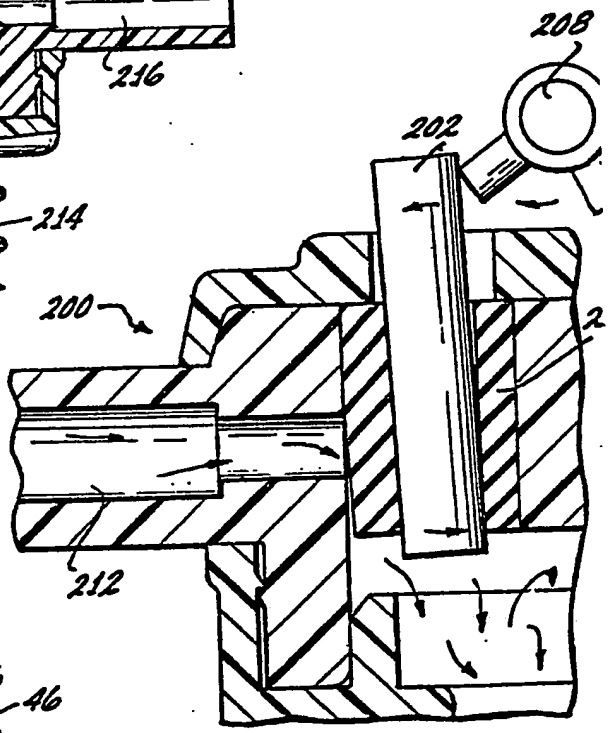

FIG. 12

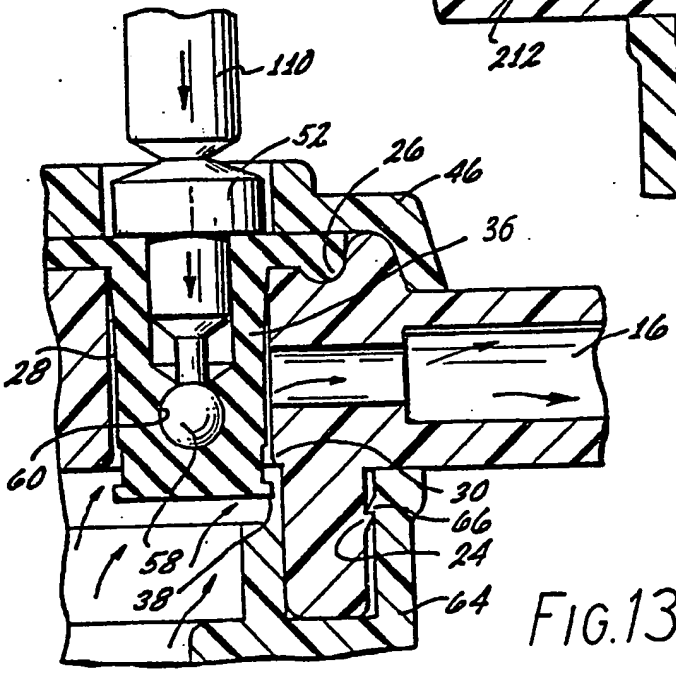

FIG. 13

SPECIFICATION

Pump with removable cassette for feeding fluid to a patient

The present invention relates to a pump for feeding fluid to a patient. The pump comprises a pump mechanism and a sealed cassette removably attached to the pump mechanism.

After a patient has had an operation and is recuperating, fluids are introduced to a patient to increase the rate of recovery. Such fluids may constitute sources of energy such as forms of sugar to provide sustenance to the patient or may constitute drugs to combat diseases or may constitute water to maintain the equilibrium of the body. The fluid may be introduced enterally such as through the stomach or parenterally such as intravenously.

Considerable strides have been made in recent years in providing apparatus for introducing fluid intravenously such as at a precise rate and in a precise volume. For example, intravenous fluid is introduced on a precise basis and in a controlled volume by the use of a pump and cassette such as disclosed and claimed in U.S. Patent 3,985,133 issued on October 12, 1976. The pump operates to pass fluid through the cassette to the patient. The cassette is disposable so that it is used only for a particular period of time such as approximately twenty-four (24) hours and is used only for a single patient. The pump and cassette disclosed and claimed in patent 3,985,133 have been so successful that they are now recognized as the standards of the industry.

This invention also provides a pump and a cassette which operate to obtain the passage of fluid through the cassette at a precise rate in a controlled volume to a patient. The cassette is constructed to provide a bacterial seal even while fluid is being transferred from a source to the cassette or from a cassette to a patient. The cassette is able to provide this bacterial seal because it has no moving parts and because it has no parts which communicate with the fluid and the atmosphere. Since the cassette provides a bacterial seal under all circumstances, the cassette can be used for the enteral introduction of fluid to a patient as well as for the parenteral introduction of fluid to the patient.

In one embodiment of this invention, a disposable cassette is constructed to pass fluid from a source to a patient. The cassette includes a hollow body made from a rigid material and having an inlet and an outlet communicating with the hollow body. A bellows member is operatively coupled to the body and defines a closure which communicates with the body and reciprocates in a direction for expanding and reducing the space within the body and the bellows. The bellows defines a bacterial seal with the body.

First valve means are operatively coupled to the body at the inlet and define a bacterial seal within the body and have first and second operative relationships. The first valve means are operative in the first relationship to provide for a flow of fluid through the inlet to the space within the body and the bellows and are operative in the second relationship to prevent such a flow. Second valve means are operatively coupled to the body at the outlet and define a bacterial seal with the body. The second valve means have first and second operative relationships and operate in the first relationship to provide for a flow of fluid to the outlet from the space within the body and the bellows and operate in the second relationship to prevent such a flow. The first and second valve means are constructed to provide for an operation of one of the valve means in the first relationship and the other one of the valve means in the second relationship.

The disposable cassette is constructed to be operated by a pump. The pump includes a stepper motor and a housing supporting the stepper motor. The control member is made from a resilient material and is provided with a pair of transverse arms disposed in a spaced parallel relationship and with a leg extending in a particular direction and joining the arms at an intermediate position along the length of the arms. The arms of the control member are attached to the housing at the corners of the legs.

First cam means are operatively coupled to the stepper motor for converting the rotary motion of the stepper motor to a linear motion in the particular direction. Means are operatively coupled to the first cam means for providing for a coupling to the resilient means to obtain an expansion and contraction of the resilient means in the particular direction. Second cam means are operatively coupled to the stepper motor for providing for an operation of the valve means.

In the drawings:

Figure 1 is a front elevational view of a pump with a removable cassette for introducing fluid to a patient;

Figure 2 is an enlarged exploded perspective view of the cassette shown in Figure 1;

Figure 3 is an enlarged sectional view in elevation of the pump mechanism shown in Figure 1 and also illustrates the cassette in coupled relationship to the pump mechanism;

Figure 4 is an enlarged elevational view of certain components included in the pump mechanism with the elements in position for providing for a passage of fluid to a cassette from source;

Figure 5 is an enlarged elevational view, partially in section, of the cassette, with the elements in position to provide for passage of fluid into the cassette, and also illustrates certain elements in the pump mechanism for operating associated elements in the cassette;

Figure 6 is an enlarged elevational view similar to that shown in Figure 4, of certain components included in the pump mechanism with the elements in position for providing for a passage of fluid from the cassette to a patient;

Figure 7 is an enlarged elevational view, similar to that shown in Figure 5, with the elements in position to provide for a passage of fluid from the

cassette;

Figure 8 is an enlarged elevational view of certain other components in the pump and illustrates such other components in one position;

Figure 9 is an enlarged elevational view of the components shown in Figure 8 and illustrates such components in another position;

Figure 10 is an enlarged fragmentary sectional view of a cassette with certain elements in position for obtaining a transfer of fluid from the cassette;

Figure 11 is a fragmentary sectional view of certain components in a cassette forming another embodiment of the invention;

Figure 12 is an enlarged fragmentary sectional view showing the operation of a valve in the embodiment of Figure 11; and

Figure 13 is an enlarged fragmentary sectional view of a cassette forming a third embodiment of the invention and particularly illustrates the operation of a valve included in this embodiment.

In the embodiment of the invention shown in Figure 1 through 10, a cassette generally indicated at 10 is included. The cassette 10 includes a body 12 preferably made from a rigid material such as an acrilonitrile. The body 12 includes an inlet 14 and an outlet 16. The body 12 also includes a downwardly turned flange 22 to define a chamber 23 and further includes a detent 24 on the outer surface of the flange. The body 12 also includes a socket 26 in its upper surface. The body 12 is further provided with a pair of recesses 28 each of which defines a seat 30 at its bottom surface.

A pair of volve members 34 made from a resilient material such as a silicone rubber are in integral relationship and are supported by the body. Each valve member 34 has a closure portion 36 which extends into an associated one of the recesses 28 and has a lip 38 for engaging the valve seat 30. The valve member 34 also has a support portion 40 which is disposed on the body 12 at a position above the inlet 14 and the outlet 16. A projection 42 extends from the support portion 40 into the socket 26.

A closure member 46 made from a rigid material such as acrilonitrile is disposed on the body 12 as by a pressed fit relationship and is suitably attached to the body 12 at its bottom surface as by ultrasonic welding. Since the closure member 46 is pressed fit onto the body 12 and is then sealed to the body, a bacterial seal is produced between the body 12 and the support portion 40 of each valve member 34. This bacterial seal is facilitated by the disposition of the projection 42 in the socket 26.

The closure member 46 is provided with apertures 50 at positions adjacent the closure portions 36. A cap 52 of an actuating rod 54 is disposed in each individual one of the apertures 50. Each rod is also provided with a ball portion 58 which is received in a socket 60 in the closure portion 36.

A hollow retainer generally indicated at 62 and made from an elastomeric material such as a low density polyethylene is constructed to be supported by the body 12. The retainer 62 includes an outer flange 64 having a detent 66 for engagement with the detent 24 to hold the retainer in fixed relationship to the body. The retainer 62 also includes an inner tongue 68 spaced from the flange 64 by a distance to provide for a pressed fit relationship between the tongue 68 and the flange 22 at surfaces 70 (Figure 5). This pressed fit relationship creates a bacterial seal between the body 12 and the retainer 62 at a position below the inlet 14 and the outlet 16.

The retainer 62 includes a bellows 72 at a position below the tongue 68. The bellows 72 is provided with thickened corrugations to increase the linearity between the amount of expansion and contraction of the bellows and the volume of fluid flow into or out of the retainer. The retainer 62 is also provided with a portion 74 shaped to become coupled to a drive member (to be described subsequently) to expand or contract the bellows 72.

A pump mechanism generally indicated at 80 (Figures 1 and 3) is adapted to operate in conjunction with the cassette 10 to obtain a controlled transfer of fluid from a source 82 to a patient 84. The pump 80 includes a stepper motor 86 supported on a housing 88. The motor 86 has a drive shaft 90 which drives a cam plate 92. The cam plate 92 (Figure 3) includes a cam track 94 which controls the movement of a cam follower 96. A lever arm 98 is coupled to the cam follower 96 for a linear movement on a reciprocal basis. A shaft 100 is in turn supported at the upper end of the lever arm 98 for movement with the lever arm. A rocker arm 102 is coupled at one end to the shaft 100 and at the other end to a rotary shaft 104.

A drive ring 106 (Figures 5 and 7) is supported by the shaft 104 and is provided with a rectangular configuration to engage a pair of tappets 108 and 110. The tappets 108 and 110 are respectively spring loaded as at 112 and 114 to move their associated tappets upwardly in a direction away from the adjacent actuating rods 54. The tappets 108 and 110 are respectively engaged by opposite ends of the drive ring 106 to position one of the tappets downwardly against the associated actuating rod and to provide for the displacement of the other tappet upwardly from the associated actuating rod.

The cam plate 92 also includes a cam track 114 (Figure 3). A cam follower 116 is disposed in the cam track 114 for a linear movement in a vertical direction in accordance with the rotation of the cam track 114. The cam follower 116 is coupled to a strain gage 118 and a control member 120 as by a screw 122. The strain gage 118 may be made from a suitable material such as a resilient steel. The strain gage 118 is rigidly attached to a leg 124 of the control member 118 as by screws 126.

The control member 120 (Figures 4 and 6) may be made from a resilient material such as a low density polyethylene. The control member 120 is

provided with a pair of arms 130 disposed in spaced and parallel relationship. The extremities of the arms 130 are attached to a fixed member 132 as by screws 134 at its opposite extremities. The leg 124 is integral with the arms 130 at intermediate positions along the lengths of the arms. The leg 124 is attached to one end of a coupling member 136 (Figure 3), the other end of which is coupled to the portion 74 at the bottom of the retainer 62.

The cam plate 92 is provided with apertures 140 Figures 4 and 6) at spaced positions around its annular periphery. A light source 142 may be disposed on one side of the cam plate 92. A light sensor 144 is disposed on the other side of the cam plate 92 to sense the movement of the apertures 140 past the light source. The signals produced by the light sensor 144 may be counted by a counter (not shown) to indicate the amount of fluid being introduced to a patient.

The stepper motor 86 operates to rotate the cam plate 92. As the cam plate 92 rotates, the cam follower 96 moves the lever arm 98 in one of two opposite directions respectively indicated in Figures 8 and 9 by arrows 148 and 150 within the lever arm. The lever arm 98 in turn drives the rocker arm 102 in a reciprocating movement about the shaft 94 as a fulcrum. This reciprocating movement of the rocker arm 102 may be seen from the relative positions of the rocker arm in Figures 8 and 9. As the rocker arm 102 reciprocates, it reciprocates the ring 106. This causes the tapper 108 to move downwardly and the tappet 110 to be simultaneously released for upward movement, or the tappet 110 to move downwardly in the other reciprocating movement and the tappet 108 to be simultaneously released for upward movement.

When the ring 106 has the position shown in Figure 5, the tappet 108 is positioned downwardly to press the associated actuating rod 54 downwardly. This causes the associated valve member 34 to become distended and the associated lip 38 to become displaced from the valve seat 30. As a result, fluid is albe to flow through the inlet 14 into the chamber 23. However, fluid is not able to flow from the chamber 23 into the outlet 16 because the associated valve member 34 is not distended.

Upon a reciprocatory movement of the ring 106 to the position shown in Figure 7, the tappet 110 becomes displaced downwardly so that the associated valve member 34 becomes distended. This allows fluid to flow from the chamber 23 into the outlet 16. However, fluid is not able to flow at this time through the inlet 14 into the chamber 23 because the valve associated with the inlet is closed.

As previously described, a bacterial seal is produced between the support portion 40 of each valve member 34 and the body 12. The production of this bacterial seal is facilitated because the support portion 40 is transverse to the closure portion 36. The production of the bacterial seal is further facilitated by the provision of the socket 26 and the disposition of the projection 42 in the socket. The socket 26 and the projection 42 facilitate the production of the bacterial seal because they increase the length of the path for the leakage of fluid and provide changes in the direction of such fluid leakage.

As will be seen from the above discussion and from the drawings, the actuating rods 54 distend their associated valve members 34 without extending into the chamber 23. The valves are opened and closed by a distention and contraction of the valve members 34, which communicate with the chamber 23 regardless of their position. As a result, the valves are opened and closed without affecting the bacterial seal produced in the chamber.

The bellows 72 is expanded and contracted in synchronism with the opening and closing of the valves defined in part by the valve members 34. For example, the bellows 72 is expanded during the time that fluid is flowing through the inlet 14 into the chamber 23. In like manner, the bellows 72 is contracted during the time that fluid is flowing through the outlet 16 from the chamber 23. The rate of transfer of fluid between the bellows 72 and one of the inlet 14 and the outlet 16 is linearly related to the rate of expansion or contraction of the bellows 72. This is facilitated by increasing the thickness of the walls of the bellows 72.

As will be seen, the bellows 72 is expanded or contracted by driving the coupling member 136 downwardly or upwardly. The expansion or contraction of the bellows 72 is obtained entirely from the movement of the coupling member 136 externally to the bellows. As a result, the transfer of fluid into and out of the bellows occurs without any positioning of any member partially in contact with the fluid in the retainer 62 or the chamber 23 and partially in contact with the atmosphere. This causes the bacterial seal to be maintained between the retainer 62 and the body 12 regardless of any expansion or contraction of the bellows.

The cassette accordingly provides a bacterial seal at all times to prevent any bacteria from communicating with the atmosphere. This results in part from the bacterial seal produced between the body 12 and the valve member 34 at a position above the inlet 14 and the outlet 16. It also results in part from the bacterial seal produced between the body 12 and the retainer 62 at a position below the inlet 14 and the outlet 16.

In order to provide a transfer of fluid directly related to the expansion and contraction of the bellows 72, the displacement of the bellows should be restricted to the vertical direction. This is accomplished by the inclusion of the control member 120. Because of the disposition of the arms 130 in the form of a parallelogram and the provision of resilient properties for the arms, the movement of the leg 134 is restricted to a vertical direction. Since the coupling member 136 is coupled to the leg 134 and the bellows 72 is in

turn coupled to the member 136, the bellows 72 is able to expand or contract only in the vertical direction.

The strain gage 118 is included to determine if any constraint is being imposed upon the bellows 72 in a direction other than the vertical direction. Electrical circuitry of a conventional nature may be coupled to the strain gage 118 to provide an alarm or to discontinue the operation of the pump when the constraint on the strain gage in a direction other than the vertical direction exceeds a particular level.

The amount of fluid cumulatively transferred to the patient may be determined by counting the number of pulses generated by the sensor 144 as the apertures 140 move past the sensor. The rate of transfer of the fluid to the patient may also be determined from the rate at which the signals are generated by the sensor 144. An alarm may be sounded, or the operation of the pump may be discontinued when the volume of the fluid transferred to the patient has reached a particular limit or the rate of transfer of the fluid to the patient is not within pre-selected limits.

Figures 11 and 12 illustrate a modified embodiment of the cassette shown in the previous Figures and described above. In the embodiment of the invention shown in Figures 11 and 12, a cassette generally indicated at 200 is provided with a pair of rods 202 and 204 capable of rocking in clockwise and counter-clockwise directions between a skewed position and a vertical position. Each of the rods is rocked by a rocker arm 208 corresponding to the rocker arm 102 in the previous embodiment. The rods 202 and 204 are rocked in the clockwise direction to the vertical position and are rocked in the counter-clockwise direction to the skewed position.

In the position of the rods 202 and 204 in Figure 11, the rod 202 is skewed and the rod 204 is vertical. This causes a valve associated with the rod 202 to become opened and a valve associated with the rod 204 to become closed. As a result, fluid flows through an inlet 212 into a bellows 214 but fluid is not able to flow through the valve associated with the rod 204.

When the rods 202 and 204 become rocked to the position shown in Figure 12, the rod 202 is vertical and the rod 204 is skewed. Thus, fluid is unable to flow through the valve associated with the rod 202 but fluid is able to flow through the valve associated with the rod 204. Since the bellows 214 is being contracted at this time, fluid flows through an outlet 216 from the bellows.

The operation of the valves may be facilitated by the disposition of the rod 202 within a resilient liner 218 and the disposition of the rod 204 within a resilient liner 220. The liners 218 and 220 may be made from a suitable material such as rubber. In the vertical position of each rod relative to its associated liner, the rod forms a seal with the liner. When the rod becomes skewed, it becomes separated from the liner at positions below the adjacent inlet 212 or outlet 216 so that fluid is able to flow between the associated inlet or outlet and the bellows 214.

Figure 13 illustrates a modification of the valve arrangement shown in Figures 1 through 10. In the modification of Figure 13, the valve member 34 becomes displaced from the seat 30 in a manner similar to the embodiment shown in Figures 1 through 10 when the valve member becomes distended. However, flow of fluid from the inlet 14 into the bellows 72 or from the bellows 72 into the outlet 16 now takes place not only through an annular recess surrounding the closure portion 36, as seen in Fig. 10, but also through a gap created by separation of the valve member 34 from the wall of the recess 28 when the valve member 34 is stretched by the actuating rod 52, as seen in Fig. 13.

CLAIMS

1. A pump cassette for use in a pump for feeding fluid to a patient, the cassette having a body defining an inlet and an outlet and a valve seat, a valve member of resilient material having a first portion which normally engages the seat to hold the valve closed but is moveable from the seat by deformation of the valve member and a second portion which is positioned on the body to support the valve member, and a cover member disposed on the second portion of the valve member and attached to the body to exert pressure on the said second portion to maintain a bacterial seal within the body.

2. A pump cassette as claimed in claim 1 having a second valve seat defined within the body and a second valve member of resilient material having a first portion which normally engages the second seat but is moveable from the second seat by deformation of the second valve member and a second portion which is positioned on the body to support the second valve member, and a cover member disposed on the second portion of the second valve member and attached to the body to exert pressure on the said second portion to maintain a bacterial seal within the body, said first valve member being disposed to control fluid flow from the inlet to a pump chamber and said second valve member being disposed to control flow from the pump chamber to the outlet.

3. A pump cassette as claimed in claim 2 in which the same cover member is disposed to exert pressure on the second portions of both valve members.

4. A pump cassette as claimed in claim 2 or 3 in which the pump chamber is a closed chamber of variable volume whereby fluid may be drawn in from the inlet and expelled through the outlet.

5. A pump cassette as claimed in claim 4 in which the pump chamber is enclosed by a bellows.

6. A pump cassette as claimed in claim 4 or 5 in which the chamber is defined by a flexible wall member cooperating with the body of the cassette to form a bacterial seal.

7. A pump cassette as claimed in claim 6 in

which the flexible wall member has a retainer portion press-fitted within an opening in the body to form the seal and retained in this position by engagement of a detent portion on the wall member with an external detent portion on the body.

8. A pump cassette as claimed in any of claims 4 to 7 including a coupling portion shaped for engagement by a drive member operable to expand and contract the pump chamber.

9. A pump cassette as claimed in any of the preceding claims in which the or each resilient valve member includes a socket in which is seated an operating rod for moving the valve member from its seat.

10. A pump cassette as claimed in claim 9 in which the valve member is disposed within a passage and the valve seat is formed by the wall of the passage, the valve member being stretchable by axial movement of the operating rod to displace the said first portion beyond the end of the passage.

11. A pump cassette as claimed in claim 9 in which the valve member is disposed within a passage and normally closes a port in the wall of the passage and the operating rod extends through the valve member and is tiltable to lift the valve member away from the port.

12. A pump comprising a pump cassette as claimed in any of claims 4 to 8 or claims 9 to 11 as appendant to claims 4 to 8 together with a pump drive mechanism comprising means for expanding and contracting the pump chamber and means for operating the first and second valve members alternately in synchronism with the expansion and contraction of the pump chamber.

13. A pump as claimed in claim 12 in which the cassette is removably coupled to the pump mechanism.

14. A pump as claimed in claim 12 or 13 wherein the means for expanding and contracting the pump chamber comprise a drive member coupled to the pump chamber and drivable to and fro in a particular direction.

15. A pump as claimed in claim 14 including means operatively coupled to the drive member for providing a signal if the drive member is constrained in a direction other than the particular direction.

16. A pump as claimed in claim 14 in which the drive member is mounted for linear movement in the particular direction by means of a pair of resilient transverse arms disposed in spaced parallel relationship and attached at their extremities to a fixed support.

17. A pump as claimed in claim 16 including a strain gauge arranged to indicate deviations of the drive member from the particular direction.

18. A pump as claimed in any of claims 14 to 17 including a rotary motor and a cam means coupling the motor to the drive member.

19. A pump as claimed in claim 18 including a rocker arm arranged for operation of the first and second valve members in alternation and a second arm means coupling the motor to the rocker arm.

20. A pump as claimed in claim 18 or 19 in which the motor is a stepper motor.

21. A pump as claimed in claim 20 including means for indicating the number of stops executed by the stepper motor as a measure of the volume of fluid pumped.

22. A pump for feeding fluid to a patient comprising a pump cassette removably attached to a pump mechanism, the cassette comprising a bellows defining a closed pump chamber, an inlet and an outlet, and respective valves coupling the pump chamber to the inlet and the outlet, each of the valves comprising a resillent valve member which is deformable by an actuating rod to move it between open and closed positions and the pump mechanism comprising a reciprocating drive member for expanding and contracting the bellows and a valve actuator engageable with the actuating rods of the two valves to operate them alternately so that the inlet valve is open when the bellows is expanded and the outlet valve is open when the bellows is contracted.

23. A pump cassette for use in a pump for feeding fluid to a patient, the cassette comprising a bellows defining a closed pump chamber, the bellows being expandable to draw fluid into the pump chamber from an inlet and contractable to expel fluid from the pump chamber through an outlet, and respective valves coupling the pump chamber to the inlet and outlet, each of the valves comprising a resilient valve member which is deformable by an actuating rod to move it between open and closed positions.

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